



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,526	11/13/2001	Amir Belson	BEL1015U	8014
25197	7590	06/16/2005	EXAMINER	
LEARY & ASSOCIATES 3900 NEWPARK MALL RD. THIRD FLOOR, SUITE 317 NEWARK, CA 94560			DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/992,526

Applicant(s)

BELSON, AMIR

Examiner

Leslie R. Deak

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-26 is/are pending in the application.
- 4a) Of the above claim(s) 19-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 19-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 19-26 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The originally claimed and searched device does not require the use of a waveguide rod or an acoustically reflective surface in the device. Furthermore, the newly presented devices are not configured to deliver ultrasonic energy in the manner as claimed in the amended claim 1.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 19-26 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-14, 16-18 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A method or disclosure indicating how the ultrasonic energy increases the diffusion of molecules across the membrane without altering the permeability of the membrane itself, critical or essential to the practice of the

Art Unit: 3762

invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Applicant argues that the instant invention differs from the device and method disclosed by Kost since the instant invention does not alter the membrane. However, there is no disclosure or explanation of how such an operation occurs. Therefore, the claims are not sufficiently enabled by the disclosure.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 2, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,725,776 to Kenley et al in view of US 4,780,212 to Kost et al. Kenley discloses a conventional dialysis system with a hollow fiber membrane that separates the blood path from the dialysis fluid path and an embolus detection area. Kost discloses a method for applying ultrasound waves to membranes to affect the permeability thereof. Kost discloses that his ultrasonic transducer may be used with a conventional dialysis system. Kost also discloses that aggregations of molecules may be exposed to a short burst of ultrasound to break up the larger particles. The ultrasound waves of the Kost device may be adjusted to any desired frequency and intensity, depending on the desired effect. (See columns 2, 3, 5.) Therefore, it would

Art Unit: 3762

have been obvious to one of ordinary skill in the art at the time of invention to add Kost's ultrasonic transducer to the dialysis system disclosed by Kenley in order to alter the permeability of the molecules across the membrane and break up aggregate molecules, as taught by Kost.

6. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,725,776 to Kenley et al in view of US 4,780,212 to Kost et al, further in view of DE 37 20 668 A1 to Schael. Kost and Kenley disclose the claimed apparatus with the exception of a round acoustic coupling. Schael discloses a flow sensor that uses ultrasound to monitor the flow through a hemodialysis shunt. The apparatus includes an ultrasound transducer connected to a cylindrical acoustic coupling in order to deliver the ultrasound waves to the flow conduit therein. (See Abstract, FIG 1.) With regard to applicant's limitation drawn to the separate cylindrical parts of the coupler, it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. See MPEP 2144.04. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to add a cylindrical acoustic coupler as disclosed by Schael to the cylindrical dialyzer and ultrasound apparatus disclosed by Kost and Kenley in order to facilitate the movement of ultrasound waves into the desired area of treatment, as taught by Schael.

7. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,725,776 to Kenley et al in view of US 4,780,212 to Kost et al, further in view of US 6,602,241 to Makower et al. Kost and Kenley disclose the apparatus as claimed with the exception of a waveguide rod, or electrode, that delivers ultrasound waves to the

treatment area. Makower discloses a delivery catheter that uses an electrode 52 for emitting energy to a treatment area. The electrode 52 may be used to emit ultrasound waves to permeate cell membranes (see columns 10, 100). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to add a delivery electrode to the Kost and Kenley dialysis apparatus with ultrasound in order to deliver a precise ultrasonic wave to the treatment area, as taught by Makower.

8. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,725,776 to Kenley et al in view of US 4,780,212 to Kost et al, further in view of US 5,405,614 to D'Angelo et al. Kenley and Kost disclose the apparatus as claimed wherein an ultrasonic apparatus is used to alter the permeability of a membrane. D'Angelo discloses a similar ultrasonic apparatus that alters the permeability of a membrane, skin, in order to allow molecules to pass through. D'Angelo discloses that his apparatus includes an ultrasonic waveform generator connected to the transducer that produces sine waves and is variable, indicating that it contains the circuitry to vary the waveforms. (See columns 2-4.) With regard to the limitations drawn to the presence of an operating switch, it has been held that broadly providing a mechanical means to replace other activity that has accomplished the same result involves only routine skill in the art. See MPEP 2144.04. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to add the waveform generator disclosed by D'Angelo to the ultrasound device for dialysis disclosed by Kost and Kenley in order to alter the permeability of a membrane in order to distribute molecules across the membrane, as taught by D'Angelo.

Art Unit: 3762

9. Claims 10-13 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,725,776 to Kenley et al in view of US 4,780,212 to Kost et al, further in view of US 6,180,058 to Lindsay et al. Kost and Kenley disclose an apparatus for kidney dialysis as claimed, including a thrombus/embolus detector. However, they fail to disclose a filter for removing thrombi and emboli from patient blood. Including filters in blood treatment devices is well-known in the art of extracorporeal blood circulation. Lindsay discloses an extracorporeal blood treatment device that employs a mesh filter as a means for trapping emboli in the blood before it is returned to the patient. (See columns 1, 2, and 8.) Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to add a filter to the device disclosed by Kost and Kenley in order to prevent harmful emboli from reaching the patient, as taught by Lindsay.

Response to Amendment/Arguments

10. Applicant's amendment filed 15 September 2004 has been entered and fully considered.

11. Applicant's arguments filed 15 September 2004 have been fully considered but they are not persuasive. Applicant has added limitations drawn to a process that is not sufficiently enabled by the specification. Thus, the pending claims have been rejected under 35 USC 112. In the alternative, the claims have also been rejected over the prior art of record.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lrd

6 June 2005